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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/891,517	06/27/2001	Ryuichiro Kurane	210352US0X	8807
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EXAMINER	
MAHATAN, CHANNING	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No.	Applicant(s)	
	09/891,517	KURANE ET AL.	
	Examiner	Art Unit	
	Channing S Mahatan	1631	

-- The MAILING DATE of this communication appears on the cov r sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) 1-22, 29-41 and 43-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-25 is/are rejected.
- 7) ☒ Claim(s) 23, 26-28 and 42 is/are objected to.
- 8) ☒ Claim(s) 1-54 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1 Sheet</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION*APPLICANTS' ELECTION*

Applicants' election with traverse of Group IX (claims 23-28 and 42; drawn to a fifth method, PCR-based) in the response, filed 09 October 2003, is acknowledged. The traversal is on the ground(s) that "the Office has not provided adequate reasons and/or examples to support a conclusion of patentable distinctness between the identified groups". This is not found persuasive because the "Election/Restrictions" requirement previously set forth indicated independent and distinct products, methods, and materially different processes of using that product. Groups I-IV are four (4) separate product groups represented as probe sets (1-4), wherein the probe sets provide product limitations that are distinguishable between the products (i.e. no stem loop structure, existence of a particular nucleotide, probe-nucleic acid hybrid complex, location of label on probe). Groups V-XVI are different methods, wherein the methods have differing steps, differing goals, and uses differing products to differing ends (i.e. measurement of fluorescence intensity, measurement of fluorescence change, determination of polymorphism and/or mutation, etc.). Groups I-IV and V-XVI are related as product and process of use, wherein the products of Groups I-IV can be used in the any of the claimed methods of Groups V-XVI. Applicants are directed to the "Election/Restriction Requirement" indicating reasons for distinctness between the identified groups. The requirement is still deemed proper and is therefore made FINAL.

Additionally, the "Election/Restriction Requirement" stated "The claims have been placed in groups to the best of the examiner's ability to decode the improper dependencies of the multiplicity of claims." Applicants' were advised to review the claims, and appropriately amend

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the claims in the groups elected. However, no amendments to resolve the improper dependencies have been presented.

Claims 1-22, 29-41, and 43-54 are withdrawn from further consideration pursuant to 37 C.F.R. § 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicants timely traversed the restriction (election) requirement in the Office Action mailed 09 September 2003.

AMENDMENT TO THE SUBSTITUTE SPECIFICATION

Applicants have indicated the substitute specification has been amended for clarity and to correct typographical errors. However, said amendments have not been entered because there did not appear to be any disclosure or contemplation for these amendments to the specification. It is believed by the Examiner that the amendments represent New Matter in the absence of particular support. For instance, the amendment to replace the paragraph at page 66, lines 4-11, particularly by deleting “decrease” and replacing such language with “change” broadens the scope of the original specification wherein “change” is interpreted to encompass both “decrease” and “increase”.

OBJECTION TO CLAIMS

Claims 26-28 and 42 are objected to under 37 C.F.R. § 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim and must refer in the alternative only (claims 26 and 27). See M.P.E.P. § 608.01(n). Accordingly, the claims have not been further treated on the merits.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 23-25.

Claims Rejected Under 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23-25 are rejected under 35 U.S.C. § 102(b) as being anticipated by Liu et al.

Liu et al. describes a quantitative molecular technique for rapid analysis of microbial community diversity in various environments by employing PCR for amplification and terminal restriction fragment polymorphism analysis (Abstract; pages 4516-4517, beginning on line 12 of the right column; and the 'Materials and Methods' section on page 4517). Thus, Liu et al. anticipates the claimed invention.

Claims 23-25 are rejected under 35 U.S.C. § 102(b) as being anticipated by Aynacioglu et al.

Aynacioglu et al. describes the analysis of polymorphisms of B2AR on a group of subjects by polymerase chain reaction-restriction fragment length polymorphism (PCR-RFLP) (Abstract; page 762 'Methods' section). Thus, Aynacioglu et al. anticipates the claimed invention.

Claims 23-25 are rejected under 35 U.S.C. § 102(b) as being anticipated by Zhang et al.

Zhang et al. describes the quantitative analysis by polymerase chain reaction-single strand conformation polymorphism (PCR-SSCP) of all the exons of two TSC genes in peripheral blood leukocytes from a patient (Abstract). Exons were amplified by PCR and PCR products were subjected to single-stranded conformational polymorphism analysis for quantification

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(pages 369-370, beginning on the left column line 26). Thus, Zhang et al. anticipates the claimed invention.

Claims 23-25 are rejected under 35 U.S.C. § 102(b) as being anticipated by Sreevatsan et al.

Sreevatsan et al. describes the screening of hepatitis C virus genotypes by employing cleavage fragment length polymorphism (CFLP), wherein clinical samples received for HCV reverse transcription-PCR were genotyped by this method (Abstract). Patient samples were amplified by utilizing a 244 base pair amplicon from the 5' untranslated region of the HCV genome and cleavage fragment length polymorphism analysis was performed on the amplified products ('Materials and Methods' section page 1896). Thus, Sreevatsan et al. anticipates the claimed invention.

No Claims Are Allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: *January 22, 2004*
Examiner Initials: *CSM*

Marianne P. Allen
MARIANNE P. ALLEN
PRIMARY EXAMINER
AC1631